



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,989	01/25/2005	Lars Wik	55320.001091	7254

21967 7590 10/06/2009
HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT	PAPER NUMBER
----------	--------------

3735

MAIL DATE	DELIVERY MODE
-----------	---------------

10/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,989	Applicant(s) WIK, LARS	
	Examiner CHRISTIAN Y. JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/7/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The IDS submitted on March 7th, 2005 has been considered in full.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specifications fail to provide support for using 0.5 ohms as a threshold level for detected impedance values.

Claim Objections

4. Claims 1, 2, 4-9, and 14 are objected to because of the following informalities: The claims include reference characters which are enclosed within parentheses. The use of reference characters is considered as having no effect on the scope of the claims. Since the reference characters are not afforded patentable weight, the reference characters enclosed within parentheses apparently should be deleted from the claims. Correction is requested.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3735

6. Claims 6-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. As to claim 6, the claim states a feature of adopting a first impedance measurement if there is no threshold value in lines 3 and 4. It is unclear how there would be no threshold value. It is also dependent upon claims that already utilize an established threshold value and would not further limit those claims.

8. As to claim 15, steps a and b have been truncated during the submission process. For purposes of examination, the examiner will utilize the claims found in the PCT of the instant application, where steps a and b comprise; a) analyzing the impedance signals to identify changes in impedance, and b) comparing the impedance changes to a predetermined threshold value.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2, 4, 5, 10, 11, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wodicka et al. (USP #5,445,144) in view of Pross et al. (USP #4,449,537).

11. As to claims 1, 2, 4, 5, and 15, Wodicka teaches an apparatus and corresponding method for providing an indication of the placement of an endo-tracheal

Art Unit: 3735

tube for ventilation (col. 5 lines 32-47) comprising a processing unit (col. 4 lines 15-43), a power source (inherent in a electrical device), a display or alarm device (col. 5 lines 32-47) characterized in that a correct or incorrect placement of the tube is indicated by the processing unit and shown on the display or indicated by activation of an alarm (col. 14, lines 26-49). Wodicka fails to teach a measuring unit for measuring the impedance amplitude with at least two measuring electrodes and using the change in impedance to indicate incorrect placement of the tube. Pross teaches a respiration monitor using thoracic electrodes to determine the impedance (col. 2 lines 34-49), compares the impedance to a threshold value (Abs), and produces an alarm if the minimum threshold value is not reached (col. 1 lines 28-39). Since incorrect placement of an endo-tracheal tube can easily lead to associated complications that may result in the patient's death, (as intubation is done to ensure that the airway is not closed off such that the air is able to reach the lungs in an anesthetic, intensive care, or emergency medicine setting, incorrect placement leads to oxygen deprivation to the patient -

<http://en.wikipedia.org/wiki/Intubation>), the identifying, positioning, and maintaining correct positioning of the tube is vital, and as such, there are many proposed solutions to solve this problem in the field of endeavor. Since thoracic impedance can give insight into the respiration parameters of a patient, incorrect placement of the tube will allow for the impedance signals to quickly indicate that the positioning of the tube is incorrect, and as a result, the patient's respiration signals are not within acceptable range. As such, it would have been obvious to one of ordinary skill in the art to modify the tube placement apparatus taught by Wodicka to utilize a thoracic impedance measurements

Art Unit: 3735

as taught by Pross to enable the detection of tube placement without invasive means as a substitute to an acoustics based monitoring.

12. As to claim 10, Wodicka teaches the monitoring over time (col. 3, lines 4-11).

13. As to claim 11, Wodicka teaches a display alarm which inherently emits light (col. 1, lines 28-39).

14. As to claim 14, Wodicka teaches an endo-tracheal tube for ventilation (10).

15. As to claim 16, Wodicka teaches a storage unit (96).

16. As to claim 17, Wodicka teaches a switch to start or stop the process (col. 13, lines 16-30).

17. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wodicka et al. (USP #5,445,144) in view of Pross et al. (USP #4,449,537).

18. As to claim 3, the combined teachings of Wodicka and Pross fail to teach the use of 0.5 ohms as a threshold level. Pross teaches the setting of a threshold value between 0.1 and 0.3 ohms. (col. 3 lines 3-18). The applicant provides neither criticality nor reasoning for why 0.5 ohms is a better threshold than other values. As such, it would have been an obvious matter of design choice to a person of ordinary skill in the art to set the threshold at 0.5 ohms as applicant has failed to disclose that the specific value of 0.5 ohms provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have thus recognized that 0.5 ohms would work equally as well as the values taught by Pross, and it would have been prima facie obvious to modify the combined teachings of Wodicka and Pross to utilize 0.5

Art Unit: 3735

ohms as a threshold because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Wodicka and Pross.

19. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wodicka et al. (USP #5,445,144) and Pross et al. (USP #4,449,537), and in further view of Webber (US 2003/0109795).

20. As to claim 6, Wodicka and Pross fail to teach the use of a first impedance measurement by adopting the value as the threshold value. However, Webber teaches the setting of a threshold based on an immediately previous measurement ([0018]). As such, absent an already established threshold, it would have been obvious to one of ordinary skill in the art to modify the tube placement apparatus taught by Wodicka incorporating the use of thoracic impedance measurements as taught by Pross with the use of a previous measurement as a threshold value as taught by Webber in order to provide a threshold value that is set to individual characteristics.

21. As to claim 7, Wodicka teaches a memory unit (96).

22. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wodicka et al. (USP #5,445,144), Pross et al. (USP #4,449,537), and Webber (US 2003/0109795), and further in view of Harada et al. (USP #5,653,241).

23. As to claim 8, the combined teachings of Wodicka, Pross, and Webber fail to teach a on/off switch with a mode for off, a single measurement, and a monitoring

Art Unit: 3735

position. However, Harada teaches a on/off switch that also incorporates a single measurement mode and a continuous monitor mode (col. 9 lines 51-57). As such, it would have been obvious to one of ordinary skill in the art to modify the tube placement apparatus taught by Wodicka incorporating the use of thoracic impedance measurements as taught by Pross and the use of a previous measurement as a threshold value as taught by Webber with a on/off switch with a single and continuous measurement mode to enable a single measurement as necessary or a continuous monitoring of the patient.

24. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wodicka et al. (USP #5,445,144), Pross et al. (USP #4,449,537), and Webber (US 2003/0109795), and further in view of Harada et al. (USP #5,653,241).

25. As to claim 9, Wodicka, Pross, Webber, and Harada fail to teach the use of 0.5 ohms as a threshold level. The applicant provides neither criticality nor reasoning for why 0.5 ohms is a better threshold than other values. As such, it would have been an obvious matter of design choice to a person of ordinary skill in the art to set the threshold at 0.5 ohms as applicant has failed to disclose that the specific value of 0.5 ohms provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have thus recognized that 0.5 ohms would work equally as well as the values taught by Pross, and it would have been prima facie obvious to modify the combined teachings of Wodicka, Pross, Webber, and Harada to utilize 0.5 ohms as a threshold because such a modification would have been

Art Unit: 3735

considered a mere design consideration which fails to patentably distinguish over the prior art of Wodicka, Pross, Webber, and Harada.

26. Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wodicka et al. (USP #5,445,144) and Pross et al. (USP #4,449,537), and in further view of Kavet et al. (US 2002/0035339).

27. As to claim 12, Wodicka and Pross fail to teach a user interface for inputting reference thoracic impedance values, threshold values, or patient characteristics. However, Kavet teaches a device with an adjustable threshold that changes the threshold to the values input by the user ([0021]). It would have been obvious to one of ordinary skill in the art to modify the tube placement apparatus taught by Wodicka incorporating the use of thoracic impedance measurements as taught by Pross with a user input interface to allow for more patient specific thresholds.

28. Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wodicka et al. (USP #5,445,144) and Pross et al. (USP #4,449,537), and in further view of Cantrell et al. (US 2001/0011159).

29. As to claim 13, Wodicka and Pross fail to teach the device integrated into a defibrillating device. Cantrell teaches a defibrillation device for use in conjunction with an endotracheal tube ([0010], [0032]). Since both devices are used in certain patients, e.g. those suffering from cardiac arrest, it would have been obvious to one of ordinary skill in the art to modify tube placement apparatus taught by Wodicka incorporating the

Art Unit: 3735

use of thoracic impedance measurements as taught by Pross to integrate a defibrillation device taught by Cantrell for use together as it would enable treatment of a patient going through ventricular fibrillation both a source of fresh oxygenated air while being treated with a defibrillator.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mehta teaches the use of impedance measurements to determine intubation positioning.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. Y. J./
Examiner, Art Unit 3735
9/25/09